Application Serial No.: 09/762,602 Amendment dated June 3, 2004

Preliminary Amendment

**Amendments to the Claims:** 

This listing of claims will replace all prior versions, and listings, of claims in the

application:

**Listing of Claims:** 

Claims 1-26 (canceled)

27. (previously presented) A method for treating sexual dysfunction in a female

subject in need of such treatment, comprising:

(a) providing a vasoactive formulation having an effective dose of a primary

vasoactive agent selected from misoprostol and misoprostol acid; and

(b) topically administering the formulation to the clitoris or vagina of the subject

for treating sexual dysfunction.

28. (previously presented) A method according to claim 27, wherein the misoprostol

or misoprostol acid is selected from the group consisting of a racemic mixture, an

enantiomer in a (+) or (-) R form and an enantiomer in a (+) or (-) S form.

29. (previously presented) A method according to claim 27, wherein the formulation

further comprises a second vasoactive agent in addition to misoprostol or misoprostol

acid.

30. (previously presented) A method according to claim 29, wherein the second agent

is alprostadil.

31. (previously presented) A method according to claim 27, wherein the formulation

further comprises: a passage accelerator for increasing absorption of at least one of

misoprostol and a metabolite of misoprostol and optionally an additional vasodilator.

32. (canceled)

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- 33. (previously presented) A method according to claim 27 32, wherein the formulation further comprises cyclodextrin.
- 34. (previously presented) A method according to claim 27, wherein treatment of sexual dysfunction further includes enhancement of sexual desire.
- 35. (previously presented) A method according to claim 27, wherein the formulation further comprises a galenic preparation.
- 36. (previously presented) A method according to claim 27, wherein the formulation is administered as one of a gel, an aqueous solution, an ointment, vaginal ovules and a system of controlled transdermal absorption.
- 37. (previously presented) A method according to claim 27, wherein the formulation comprises a gel.
- 38. (previously presented) A method according to claim 37, wherein the gel contains a polymer having a concentration of less than 4%.
- 39. (previously presented) A method according to claim 27, wherein the formulation is administered as a vanishing cream.
- 40. (previously presented) A method according to claim 27, wherein the formulation further comprises gelatin.
- 41. (previously presented) A method for treating sexual dysfunction in a female subject, comprising:
- (a) providing a mixture including misoprostol or misoprostol acid, hydroxypropyl methyl cellulose and water; and
  - (b) topically administering the mixture to a female subject.

- 42. (previously presented) A method according to claim 37, wherein the effective dose of misoprostol or misoprostol acid is in the range of 0.3-0.9% w/v and the formulation further includes hydroxypropyl methyl cellulose.
- 43. (canceled)
- 44. (canceled)
- 45. (canceled)
- 46. (canceled)
- 47. (canceled)
- 48. (previously presented) A pharmaceutical composition comprising:

  an effective dose of misoprostol compound and alprostadil in a topical

  formulation suitable for application to at least one of the clitoris and the vagina, for

  promoting tumescence of the clitoris in women suffering from sexual dysfunction,

  wherein penetration of the alprostadil to underlying tissue is facilitated by the misoprostol

  compound.
- 49. (previously presented) A pharmaceutical composition according to claim 48 wherein the formulation further comprises a methyl cellulose.
- 50. (previously presented) A method for treating sexual dysfunction in a female subject in need of such treatment comprising:

providing a vasoactive formulation including a misoprostol or misoprostol acid, but lacking a non-misoprostol penetration enhancer; and

topically administering the formulation to the clitoris or vagina of the subject such that penetration to underlying tissue is facilitated by the misoprostol or/and misoprostol acid for promoting tumescence of the clitoris.

- 51. (previously presented) A method according to Claim 50 wherein the formulation further comprises alprostadil.
- 52. (previously presented) A method according to Claim 50 wherein the formulation further comprises cyclodextrin.
- 53. (previously presented) A method according to Claim 50 wherein the formulation further comprises a gel.
- 54. (previously presented) A method according to Claim 50 wherein the formulation further comprises a methyl cellulose.
- 55. (new) A method for treating sexual dysfunction in a female subject comprising:

  providing a vasoactive formulation consisting essentially of misoprostol and/or
  misoprostol acid; and

topically administering the formulation to the clitoris or vagina of the subject for treating sexual dysfunction by stimulating vasodilation.

56. (new) A method for treating sexual dysfunction in a female subject comprising: providing a vasoactive formulation having an effective dose of active agent, the active agent consisting of misoprostol and/or misoprostol acid; and

topically administrating the formulation to the clitoris or vagina of the subject for treating sexual dysfunction.

57. (new) A method for treating sexual dysfunction in a female subject comprising:

providing a topical formulation having an effective dose of an active agent, the
active agent consisting essentially of a mixture of a misoprostol compound and
alprostadil; and

topically administering the formulation to the clitoris or vagina of the subject for treating sexual dysfunction.

58. (new) A method for treating sexual dysfunction in a female subject comprising:

providing a formulation containing an effective dose of a synergetic mixture of a first agent consisting of a misoprostol compound and a second vasoactive agent other than a histamine or histamine receptor agonist; and

topically administering the formulation to the clitoris or vagina of the subject for treating sexual dysfunction.